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PROVISIONAL APPLICATION FOR PATENT COVER SHEET - Page 1 of 2

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INVENTOR(S)					
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☐ Additional inventors are being named on _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
APPARATUS AND METHOD FOR FATIGUE TESTING OF PROSTHETIC VALVES					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
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ENCLOSED APPLICATION PARTS (check all that apply)					
☒ Application Data Sheet. See 37 CFR 1.76		☐ CD(s), Number of CDs _____			
☒ Specification <i>Number of Pages</i> 13		☐ Other (specify) _____			
☒ Drawing(s) <i>Number of Sheets</i> 6					
Total # of sheets 19		= Application Size Fee		\$0.00	
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PROVISIONAL APPLICATION COVER SHEET

Page 2 of 2

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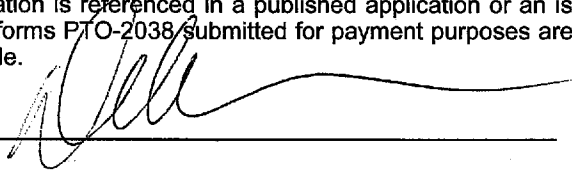


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SIGNATURE



Date

March 6, 2009

TYPED or PRINTED NAME

David G. Rosenbaum

REGISTRATION NO.
(if appropriate)

31872

TELEPHONE

847-770-6000

Docket Number:

6166-001

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	6166-001
		Application Number	
Title of Invention	APPARATUS AND METHOD FOR FATIGUE TESTING OF PROSTHETIC VALVES		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

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Applicant Information:

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Applicant Authority		☒ Inventor		☐ Legal Representative under 35 U.S.C. 117	
				☐ Party of Interest under 35 U.S.C. 118	
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	Steven		WEINBERG		
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service					
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	6166-001	
		Application Number		
Title of Invention	APPARATUS AND METHOD FOR FATIGUE TESTING OF PROSTHETIC VALVES			
Citizenship under 37 CFR 1.41(b)	US			
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Application Information:

Title of the Invention	APPARATUS AND METHOD FOR FATIGUE TESTING OF PROSTHETIC VALVES		
Attorney Docket Number	6166-001	Small Entity Status Claimed	☒
Application Type	Provisional		
Subject Matter	Utility		
Suggested Class (if any)		Sub Class (if any)	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	6	Suggested Figure for Publication (if any)	

Publication Information:

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	6166-001
		Application Number	
Title of Invention	APPARATUS AND METHOD FOR FATIGUE TESTING OF PROSTHETIC VALVES		
Customer Number	29335		

Domestic Priority Information:

This section allows for the applicant to claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c). Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status		Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)

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Application Number	Country ¹	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			☒ Yes ☐ No

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Assignee 1

If the Assignee is an Organization check here. ☒

Organization Name Biomedical Device Consultants & Laboratories of Colorado, LLC

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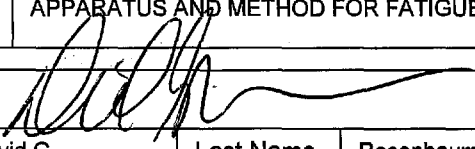
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number		6166-001	
		Application Number			
Title of Invention		APPARATUS AND METHOD FOR FATIGUE TESTING OF PROSTHETIC VALVES			
Signature				Date (YYYY-MM-DD)	
				3/6/09	
First Name	David G.	Last Name	Rosenbaum	Registration Number	31872

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TITLE:

[001] APPARATUS AND METHOD FOR FATIGUE TESTING OF PROSTHETIC VALVES

BACKGROUND OF INVENTION

[002] The present invention relates to the field of systems and methods for fatigue testing of prosthetic devices. More specifically the present invention relates to an apparatus and method for the testing of prosthetic vascular and heart valves (collectively referred to hereinafter as “valves”) under simulated physiological loading conditions and high-cycle applications. Further, the present invention provides means for imparting highly variable loading profiles to expose the device being tested to different physiological loading conditions during a testing run.

[003] Prior prosthetic valve testing apparatus and methods, such as those outlined by Swanson in U.S. Pat. No. 4,546,642 and U.S. Pat. No. 4,381,663, use a traditional rotary motor coupled with mechanisms to produce regular sinusoidal time varying pressure field conditions. To accurately simulate physiologic conditions and/or produce a more desirable test condition, especially at accelerated testing speeds, a non-sinusoidal time dependent pressure field may be desired. This is not easily accomplished with a mechanistic approach. Furthermore, current systems employ a flexible metallic bellows or conventional piston and cylinder as drive members to provide the pressure actuation. Flexible metallic bellows are not ideal because they require high forces to operate and resonate at frequency, necessitating the use of larger driving systems and limiting the available test speeds. Piston and cylinder arrangements are not ideal because the seals employed in these systems are subjected to friction and thus have severely limited life in high cycle applications.

BRIEF SUMMARY OF THE INVENTION

[004] The purpose of the present invention is to simulate physiologic loading conditions on a vascular or heart prosthetic valve under variable loading conditions. Fatigue testing is accomplished by first deploying the test valve in an appropriately sized rigid or flexible housing tube or other appropriate structure. The housing tube and valve being tested is then subjected to physiological appropriate conditions which may include: pressure, temperature, flow and cycle times. Testing and test conditions are controlled by a control computer that permits both input of test conditions and monitors feedback of the test conditions during a testing run. Computer system control may be either an open loop control that requires user intervention in the event a condition falls outside pre-set condition parameters or a closed loop control system in which the computer monitors and actively controls testing parameters to ensure that the testing parameters remain within the pre-set condition parameters.

[005] A working fluid, which may be water, saline, a saline/glycerin solution, a glycerin/water solution or a blood analog or substitute, is employed within the testing system. The working fluid may be selected to simulate one or more attributes of human blood, such as density, viscosity or temperature. For example, in certain instances, physiological saline which does not simulate the viscosity of blood, but simulates density, may be used. In other cases saline/glycerin solution may be employed to simulate blood viscosity.

[006] Plural valve housing tubes are coupled in parallel to a main housing having plural fluid distribution channels in communication with each of the plural valve housing tubes. The main housing consists generally of a single fluid reservoir in fluid flow communication with each of the plurality of valve housing tubes. The single fluid reservoir includes a lower section and an upper section, the lower section includes a plurality of fluid outlet ports, and a single fluid outlet port communicates with an inflow opening of a housing tube. The upper section includes a plurality of fluid inflow ports, a single fluid inflow port communicated with an outflow opening of a housing tube. A central return flow channel is provided between the upper section and the lower section of the fluid reservoir to provide a return flow of the working fluid from the outflow

section of the housing tubes. A throttle control and a check valve are disposed at the inflow and outflow ends of the central return flow channel, respectively, to regulate fluid flow during testing. The throttle control serves to regulate pressure across the valves being tested as well as the return flow of the working fluid in the fluid reservoir.

[007] The system of the present invention generally includes a linear actuator or magnetic based drive coupled to a flexible rolling diaphragm. The flexible rolling diaphragm impinges upon the lower section of the fluid reservoir to provide a motive force to drive the working fluid through its cycles within the main housing and the housing tubes. The flexible diaphragm is coupled to a lower opening in the main housing and is reciprocally moveable to pressurize and depressurize fluid within the lower section of the main housing. The flexible diaphragm is highly compliant with low resistance to axial deformation across its entire axial range of motion.

[008] These components operate together to act as a fluid pump and when combined with a fluid control system, provide the differential pressure and flow conditions necessary to cycle the valve. The internal conditions, which includes, among other things, temperature, differential pressure and system pressure, are electrically communicated to monitoring and controlling software on a test system computer. The motion of the fluid pump and therefore the system dynamics are controlled via test system control software. The pressure field resulting from the pump motion is easily controlled and can be set as a simple sine wave or as any complex user created waveform. Figure 9 provides examples of a three different pressure control signals generating three different cyclical pressure wave forms across a valve being tested. Because of the vertical pump orientation of the present invention, the term “upstroke” is synonymous with a pressurization stroke of the pump, i.e., that which exerts a positive pressure across the valve being tested and the term “down stroke” is synonymous with a depressurization stroke of the pump, i.e., that which exerts a negative pressure across the valve being tested. Typical test systems are only capable of driving the fluid with a regular sine wave. A non regular pressure waveform is advantageous as it allows the user to control the rate of pressurization in the test system and optimize the valve test conditions, while maintaining a desired operating frequency. Although two exemplary

non regular waveforms having short upstrokes and down strokes, respectively, are illustrated in Figure 9, it is recognized that any arbitrary pressure waveform may be generated and can be utilized to drive the pump motion. All system inputs and outputs are continuously monitored and directed into a software based alarm system, allowing the system to automatically halt if any signal deviates outside of the user set bounds.

[009] The system controller coupled with the software can be enabled to provide full closed loop control based on any of the feedback measurements. In one example of this functionality, the software can be configured to control the driving amplitude and velocity based on the differential pressure transducer feedback. The system would therefore compensate for any changes during the high cycle testing cycle providing the test valves with the most optimal testing conditions.

[010] There has thus been outlined some of the features of the invention in order that the detailed description thereof may be better understood, and in order that the present contribution to the art may be better appreciated. There are additional features of the invention that will be described hereinafter.

[011] In this respect, before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction or to the arrangements of the components set forth in the following description or illustration in the drawings. The invention is capable of other embodiments and of being practiced and carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein are for the purpose of the description and should not be regarded as limiting.

[012] A principle object of the current invention is to provide a fatigue tester capable of simulating physiologic conditions on valve prosthesis at an accelerated rate.

[013] Another object is to provide a fatigue tester which has the capability of creating either sinusoidal or non-sinusoidal pressure and/or flow waveforms.

[014] Another object is to provide a fatigue tester with a low inertia flexible rolling bellows diaphragm drive system.

[015] Another object is to provide an automated test interface capable of running without direct management, ensuring proper testing conditions and safety mechanisms.

[016] Another object is to provide a test interface capable of closed loop control based off any system measurement feedback.

[017] Yet another object of the present invention is to create a pressure waveform within a testing system that applies a pre-defined pressure gradient over time to a valve being tested.

[018] Other objects and advantages of the present invention will become obvious to the reader and it is intended that these objects and advantages are within the scope of the present invention. To the accomplishment of the above and related objects, this invention may be embodied in the form illustrated in the accompanying drawings, attention being called to the fact, however, that the drawing are illustrative only, and that changes may be made to the specific construction illustrated and described within the scope of this application.

BRIEF DESCRIPTION OF THE DRAWINGS

[019] Various other objects, features and attendant advantages of the present invention will become fully appreciated as the same becomes better understood when considered in conjunction with the accompanying drawings, in which like reference characters designate the same or similar parts throughout the several views, and wherein:

[020] Figure 1 is a partial block diagram illustrating the main testing system and its control systems in accordance with the present invention. .

[021] Figure 2 is a cross sectional view taken along line 2-2 of Figure 1 illustrating the main testing system and its internal flow path and valve configuration.

[022] Figure 3 is a partial cross sectional view taken along line 3-3 of Figure 1.

[023] Figure 4 is an enlarged front view taken at circle 4a of Figure 3 showing an upper support mechanism.

[024] Figure 5 is an enlarged front view taken at circle 5a of Figure 3 showing a lower support mechanism.

[025] Figure 6 is a cut away perspective view of a linear piston drive system and flexible rolling diaphragm pump.

[026] Figure 7 is a cut away perspective view of a shut off valve in the open position.

[027] Figure 8 is a cut away perspective view of the shut off valve in the closed position.

[028] Figure 9 is a graph depicting three exemplary pressure control waves for the control software to generate across a valve being tested.

DETAILED DESCRIPTION OF THE INVENTION

[029] Turning first to Figure 1, generally shown is the preferred embodiment of the current invention. The main fatigue testing system 10 is operably connected to a data acquisition (DAQ) device 41 and to an amplifier and control system 40. These components are, in turn, operably connected to a microprocessor based computer 42. All systems are preferably connected to an uninterrupted power supply (UPS) 43. The fatigue testing system 10 consists generally of an external housing defining a lower chamber and upper chamber and a first fluid flow pathway from the lower chamber to the upper chamber which passes through the device being tested and a second fluid flow pathway from the upper chamber to the lower chamber to return fluid from the upper chamber to the lower chamber in preparation for a following cycle. A check valve is in-line with the upper and lower chambers to regulate back flow through the apparatus. A controllable flow constrictor is also in-line with the upper and lower chambers to regulate the differential pressure across the test valves during operation.

[030] The fatigue testing system 10 is pressurized, such as by introducing pressurized air from an external air source 47, such as an air compressor or sealed pressurized volume. The system air pressure is controlled via a pressure regulator 46. Prior to pressurization, a working fluid (not shown) is introduced into the external housing substantially filling the housing. Alternatively, the system can be pressurized by first sealing the system and then changing the position of the fluid driver such that the available volume is decreased.

[031] Shown in Figure 2 is the external housing and primary fluid system and flow path. A plurality of valve containing housing tubes 29 are connected in fluid flow communication between the upper and lower chambers of the external housing as shown in Figures 1 and 2. The housing tube inner diameters preferably range from 1-50mm

with plural housing tubes 29 being coupled in parallel to the external housing for simultaneous testing of multiple valves.

[032] Fluid flow pathways 50, 52, 54, 56 within the external housing are illustrated by phantom lines in Figure 2. During the primary or pressurization (see, e.g., that portion of waveform 62, Figure 9, having positive stroke percentage values,) portion of the testing cycle, fluid is moved past the valve prosthesis within the housing tube 29 forcing the valve prosthesis to the open state. A fluid drive member or fluid pump piston 14 is provided to pressurize and drive the working fluid upward through the plenum 18. The plenum 18 also serves as a mounting point for the flexible diaphragm system. The plenum also includes fluid ports for pressure monitoring and system draining. The gate 19 and gate guide plate 20 serve as a fluid isolation valve allowing service to be performed on the drive and drive components without the need to drain the system. Figure 7 shows the gate 19 in the open configuration while Figure 8 shows the gate 19 in the closed configuration. As the test cycle progresses, the fluid moves up through base plate 11 and flow ring 44 into lower chamber 21. The fluid is blocked from entering a central return channel 33 by a one way exit valve 25. The working fluid then passes from the lower chamber 21 and into a flow conditioning chamber 24, wherein it passes through flow straightener 23, aligning the flow along the axis of the valve prosthesis. Sample adapters 27, which allow the samples tubes to be connected to the system in a leak free manner, attach the sample tubes 29 to the lower sample chamber 26. The fluid moves through the open valves 30 inside the sample tubes 29 into the upper sample chamber 31 and return chamber 45, thus completing the first portion of the test cycle.

[033] It will be understood that during the primary or pressurization portion of a testing cycle, piston 14 moves in a positive direction toward the external housing and creates an initial pressurization and fluid flow 50 passes through the lower chamber 21, impinges upon a generally conical flow baffle 22 and is directed radially outward to flow straighteners 23. From flow straightener 23, the flow encounters a narrower diameter valve conduit 29, which communicates fluid flow 52 through valve 30, being tested, directly to the upper chamber 45. A collateral pressure sensing conduit is coupled to

valve conduit 29 and directs a fluid flow pathway 54 toward a pressure transducer 28 that serves to monitor the differential pressure gradient across valve 30 within the valve conduit 29. Once the fluid flow 52 has exited valve conduit 29, flow 56 enters the upper chamber 45, passes around a throttling valve and a return fluid flow 58 is communicated through return conduit 33 to the lower chamber 21 during a secondary or depressurization portion of the test waveform.

[034] During a secondary or depressurization (see, e.g., that portion of waveform 62, Figure 9, having negative stroke percentage values) portion of the test cycle the flow is reversed and the valve 30 is closed. As the secondary portion of the cycle begins, the fluid moves through a throttling valve 32 into the central return channel 33 and back into the lower chamber 21 through the one way exit valve 25. Simultaneous to this action the valve 30 is closed due to the flow reversal and differential pressure present between the upper and lower chambers. The drive system returns to its starting position and the process is repeated, cycling the valve. A single test cycle consists of completion of both the first and secondary portions of the test cycle such that the valve passes through one open and closed cycle.

[035] Those who are skilled in the art will appreciate that the dynamics of the system can be controlled through the stroke volume of the piston 14, throttle valve 32 and compliance chamber 35. The throttle valve 32 is connected to the throttle valve handle 37, which runs through an air tight fitting on top of compliance chamber cap 36. Not shown on the compliance chamber cap are inputs for pressurized gas which ensures proper function of the flexible diaphragm system. The throttle valve handle 37 is adjustable, such as by a threaded coupling to an upper cap on compliance chamber 35. The throttle valve 32 can be adjusted up or down, increasing or decreasing the resistance to fluid returning to the central return channel 33 resulting in control of the differential pressure across the valve. The amount of gas inside the compliance chamber 35 allows the user to control the damping of the system and provides an additional tool used to obtain the ideal valve test condition.

[036] The differential pressure transducers 28 monitor the pressure field across each valve 30 sample and valve conduit 29 during the testing cycle. Flexible or rigid tubing 29 is connected to the upper and lower sample adapters 27, with the opposite ends of the sample adapters 27 being connected to the differential pressure transducer 28. Additional monitoring transducers can be introduced through the sensor ports 34 and other ports built into the return chamber 45 as necessary. The working fluid temperature is controlled via the fluid heater 38 and temperature transducer 39. Upper and lower temperature bounds are set in the test software. At startup the system will begin to heat until the upper bound is reached. As the input temperature falls below the lower bound, the heater is again activated, thus maintaining a mean temperature within acceptable bounds. This mean temperature is typically set to 37° C to simulate physiologic conditions.

[037] Figure 3 illustrates the test system support structure and primary drive components. Vibration reducing leveling feet 1 are attached to a frame 2, which provides a support structure for the upper fluid system and lower drive mechanism. A magnetic drive 5 provides the linear thrust necessary to create the fluid motion and pressure differentials requires to cycle the valve prosthesis. The drive stability structure 4 connects the drive base plate 6 to the magnetic drive 5. The thrust rod 8, which is the mobile component of the magnetic drive 5, is aligned to the system through the drive support structure as shown in Figure 5. The lower spring and extension shaft 3 allow the system to maintain the starting point position when the magnetic drive is in an unpowered state. The alignment of the lower spring and extension shaft 3 with respect to the system center is maintained through linear bearings in the stability structure 4. Moving to the upper alignment structure 7 shown in Figure 4a, the thrust rod 8 is supported and aligned with respect to the system center through a linear bearing (not shown). Mechanical hard-stops 9 affixed to the upper extension shaft 12 limit uncontrolled motion in the event of a power loss or software malfunction. The number of cycles completed during a test is monitored with a cycle counter 10 which is affixed to the upper alignment structure 7.

[038] The flexible rolling bellows diaphragm drive system is shown in Figure 6. A rigid cap 16 clamps the diaphragm 15 to the piston 14, while peripheral edges of the diaphragm are sealed between upper 17 and lower 13 bore members. The diaphragm 15 is preferably a cap-like member constructed of a non-reactive and flexible thin rubber, polymeric or synthetic based material. The flexible diaphragm is highly compliant with low resistance to axial deformation across its entire axial range of motion within the upper and lower bore members 17, 13. However, alternative configurations of the diaphragm 15 may be employed so long as the configuration is capable of very low friction and very low resistance deformation under the influence of the piston 14. Those who are skilled in the art will appreciate the many advantages of a low friction rolling bellows diaphragm as opposed to a rigid bellows or traditional piston and cylinder drive. The lateral surfaces of diaphragm 15 roll or evert as the piston 14 reciprocates within the upper 17 and lower 13 bore members. This rolling or eversion exerts very little resistance to piston 14 movement. These components are affixed to the support plenum 18 and maintain the pressure seal along the circumference of the diaphragm 15. The alignment of the upper extension shaft with respect to the system center is maintained through a linear bearing coupled to lower bore member 13.

[039] The exemplary pressure waveforms 60, 62, 64 depicted in Figure 9 may be generated by the system 10 of the present invention or by other mechanical mechanisms. It is envisioned that alternative mechanical or electromechanical systems, such as those including gearing or cams to drive a pump, may be employed in a manner that generates the variable pressure waveforms as depicted in Figure 9, in which the pressure gradients are variable over time.

[040] While the present invention has been described with reference to the particular embodiments set forth above, it will be understood by those skilled in the art that variations, such as those in construction, configuration, dimension, material selection

and assembly, may be employed without departing from the spirit and scope of the present invention, which is more fully defined with reference to the claims appended here to.

ABSTRACT OF THE DISCLOSURE

[041] An apparatus and method for testing of prosthetic vascular and heart valves under simulated physiological loading conditions. The apparatus consists generally of a plurality of housing tubes into which prosthetic valves are deployed. Each of the housing tubes is coupled, in fluid flow communication, to a common closed loop reservoir housing. A reciprocating linear drive pump having a rolling diaphragm is provided to cyclically pressurize fluid within the reservoir housing and drive the pressurized fluid through the valve device being tested. The reservoir housing defines an internal chamber having fluid outflow ports and fluid inflow ports in communication with each of the plurality of housing tubes, and check valves to regulate back pressure across the valves being tested.

Figure 1

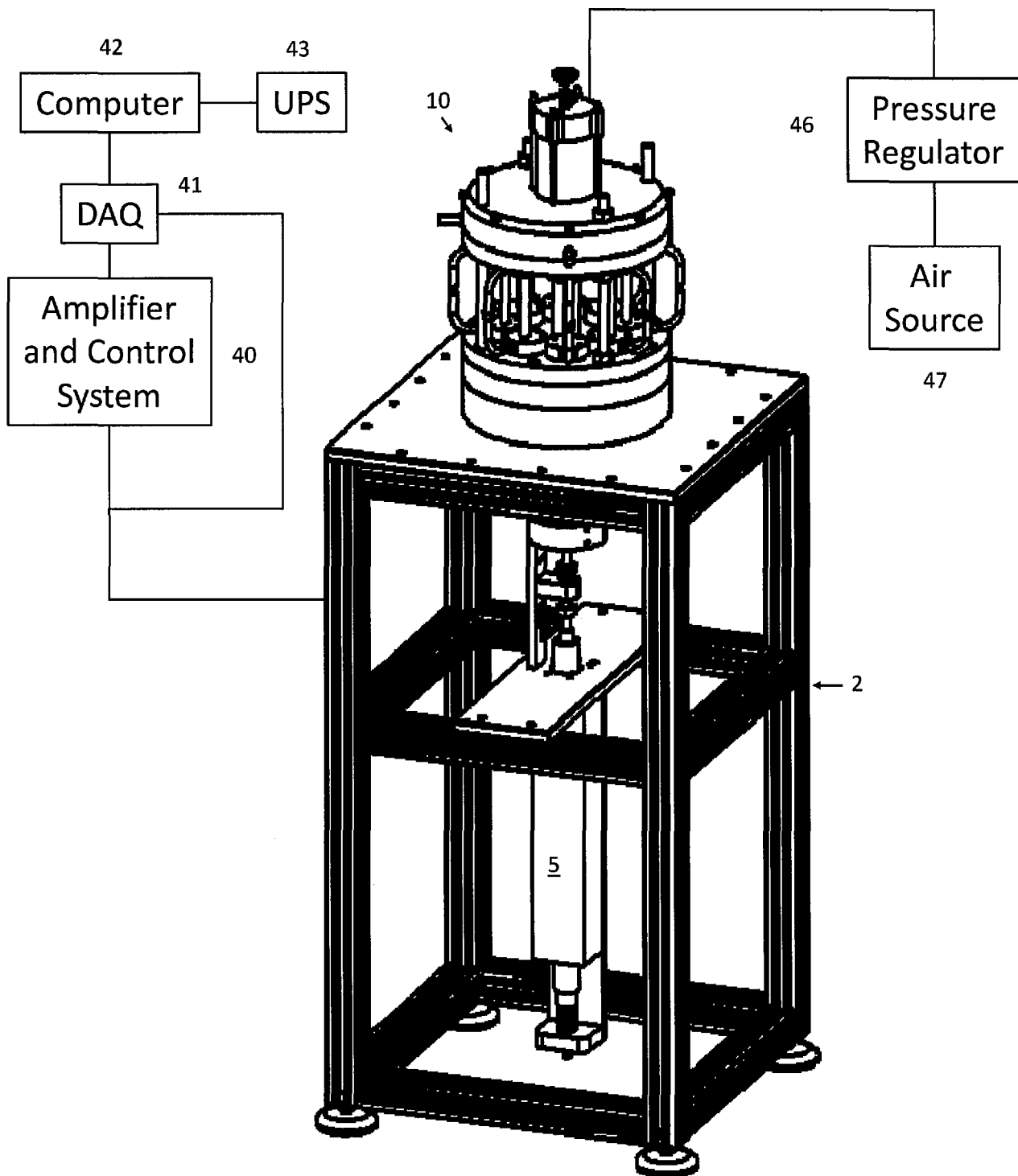


Figure 2

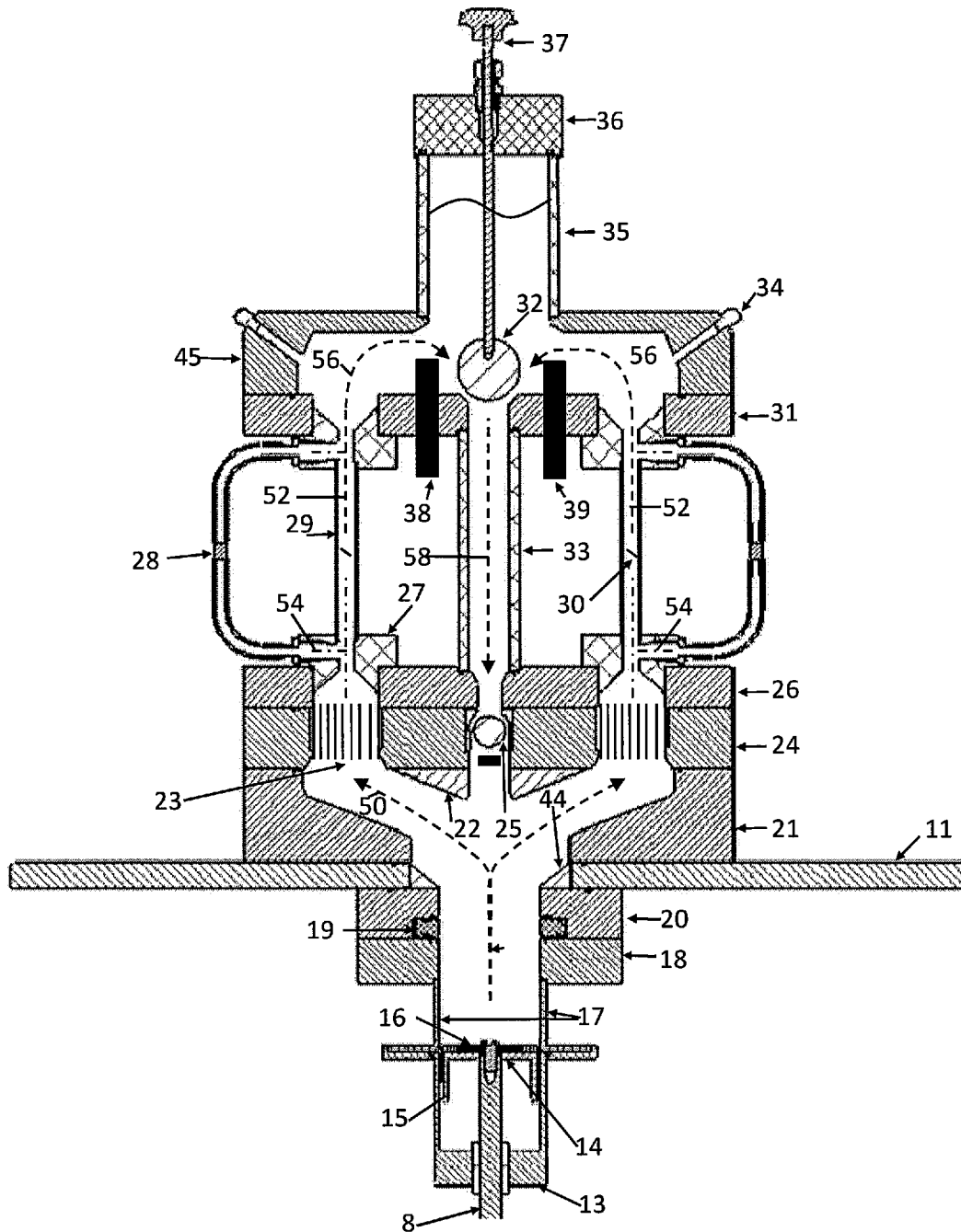


Figure 3

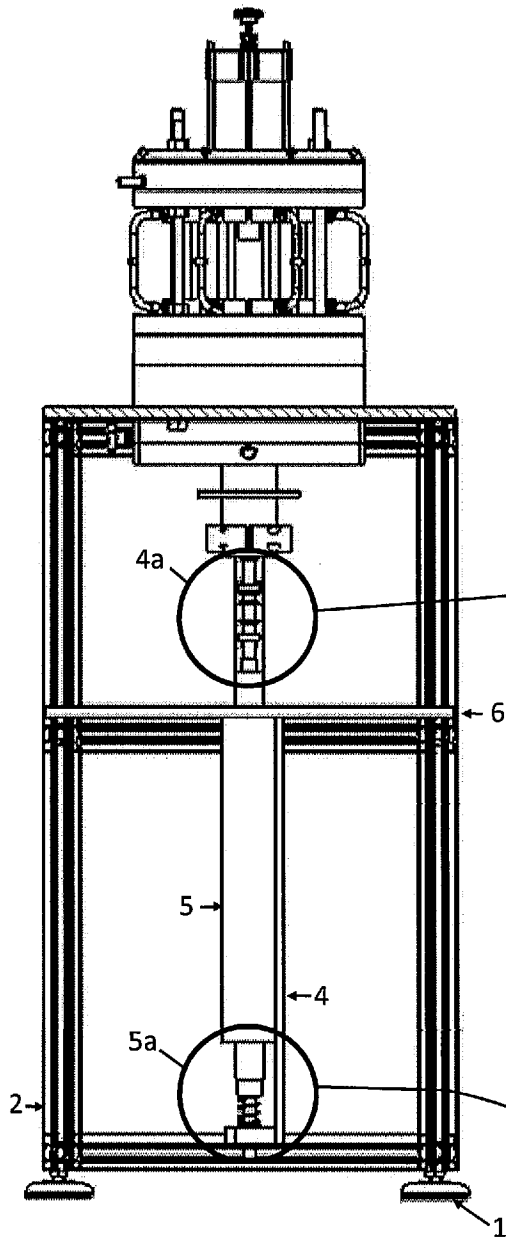


Figure 4

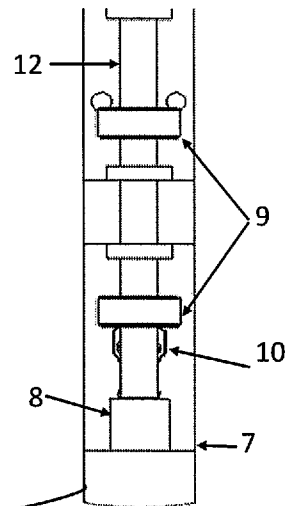


Figure 5

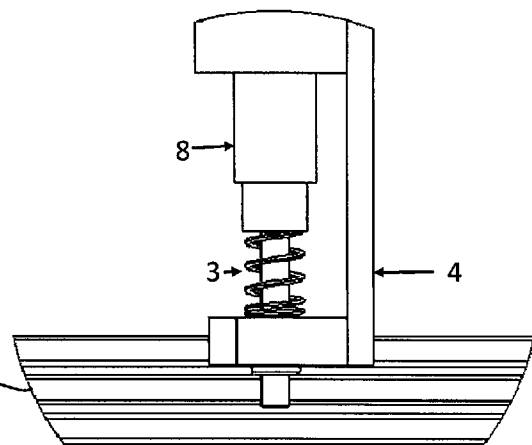


Figure 6

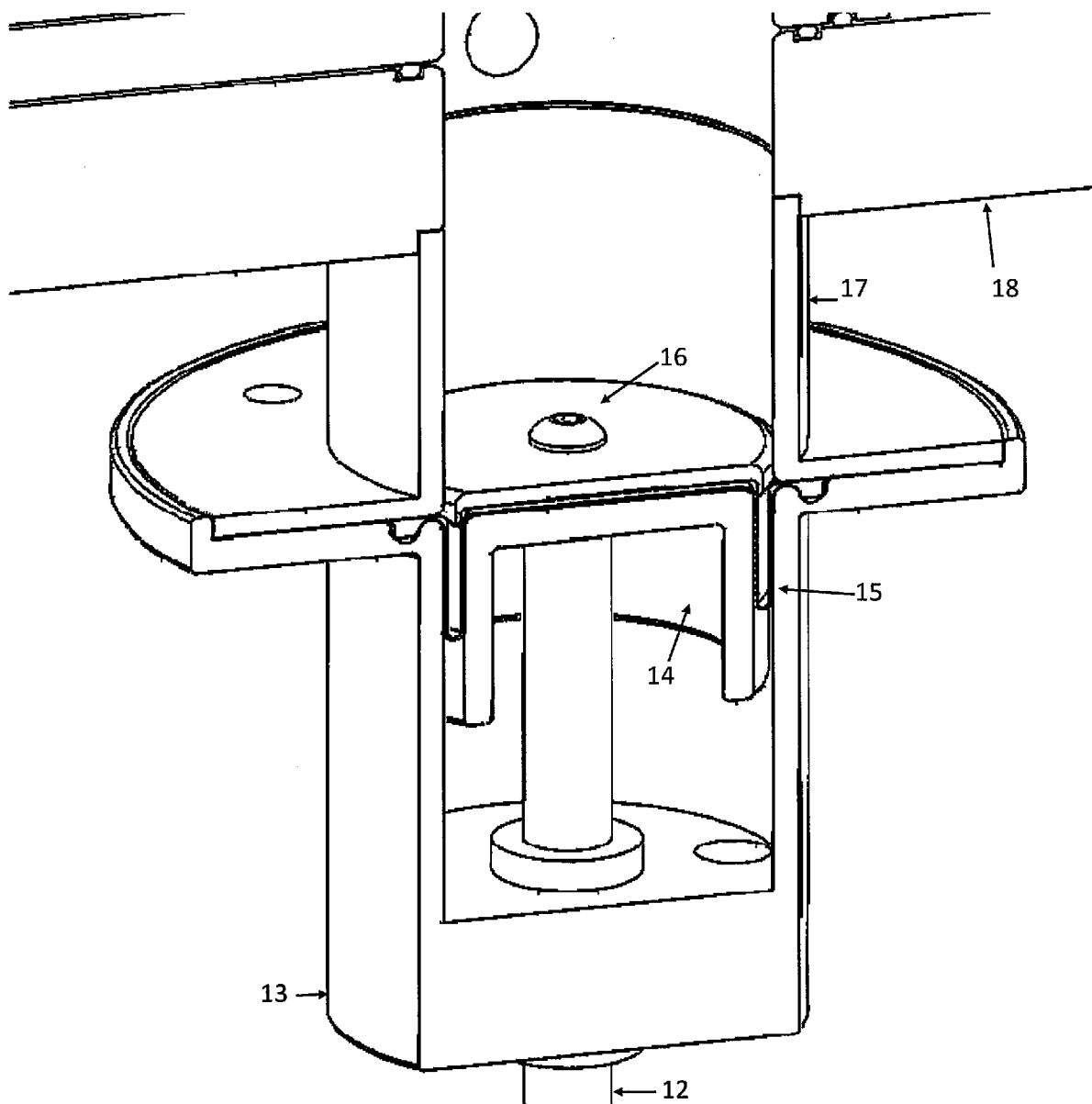


Figure 7

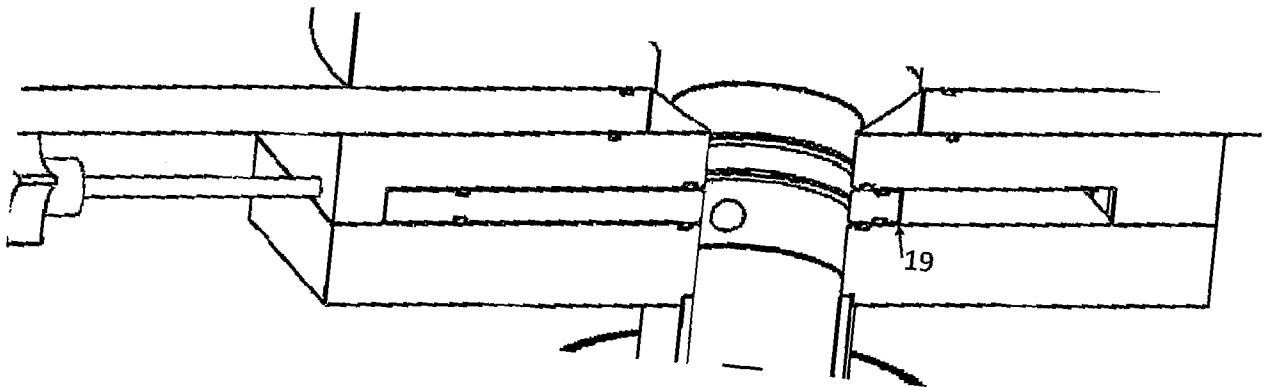


Figure 8

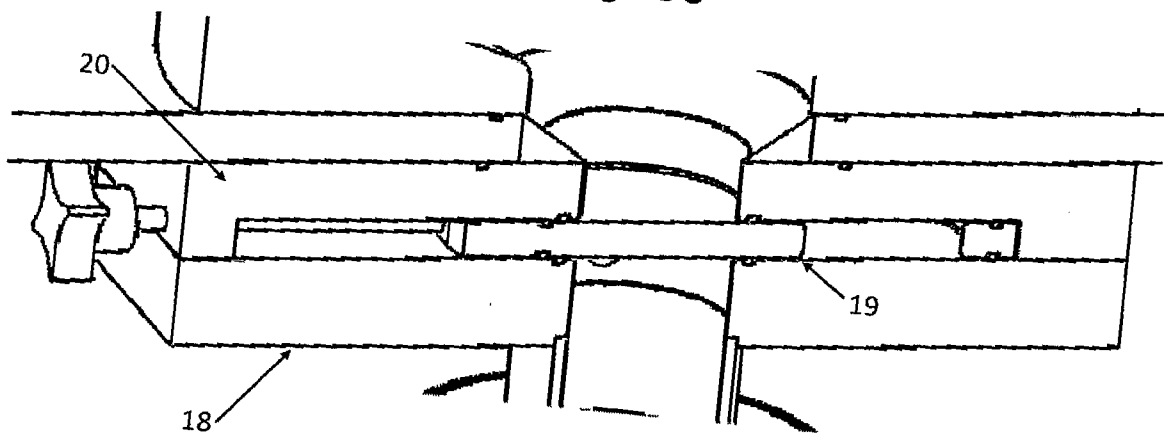


Figure 9

